

COM12120

# Cold Chain Management

Adapted from  
Immunisation Unit  
Health Protection NSW

# Cold Chain Education

## Aims:

- Raise staff awareness of Cold Chain Management
- Prevent administration of ineffective vaccines and medications
- Prevent the need to revaccinate patients

# Learning Outcomes

On completion of this session staff should be able to;

1. State the correct storage temperature for vaccines and medications
2. Identify the correct storage configuration for their vaccine and medication refrigerators
3. Identify, act upon and escalate any suspected Cold Chain breach
4. Perform temperature monitoring for their vaccine and medication refrigerator according to policy

# What is the cold chain?

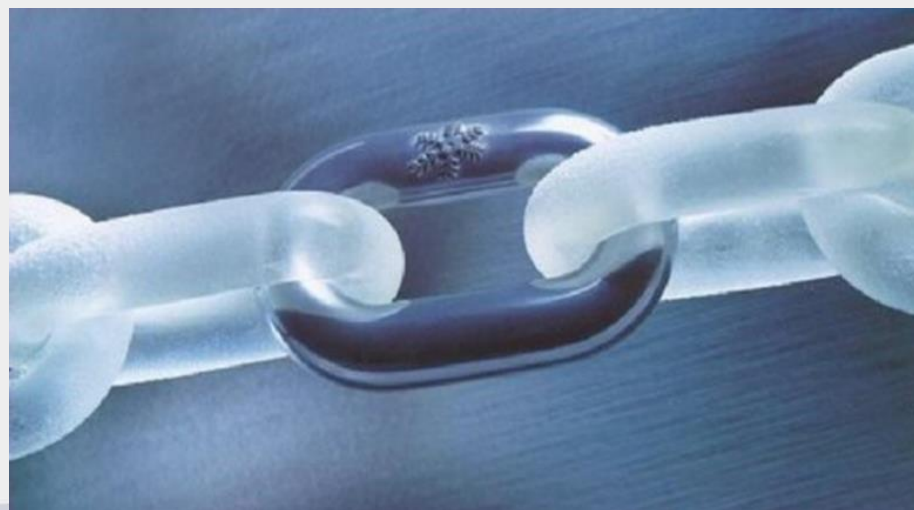
The 'cold chain' is the system of transporting and storing vaccines within the temperature range of +2°C and +8°C.

The cold chain begins from the time the vaccine is manufactured, continues through storage at the NSW State Vaccine Centre and ends when the vaccine is administered to the patient.

**The cold chain is only as strong as the weakest link**

# What is a cold chain breach?

A breach occurs when the vaccines and medications are stored outside of  $+2^{\circ}\text{C}$  and  $+8^{\circ}\text{C}$ .



Outside this range the vaccine will die and medications will not work.

# Why is Cold Chain management so important?

- Health professionals have a responsibility to ensure that clients receive effective health products (i.e. vaccines and medications that have not been adversely affected by heat or cold).
- Good vaccine management precludes the need to revaccinate clients who may, under circumstances of poor vaccine management, receive an ineffective vaccine

# What is the potential impact of a Cold Chain breach?

- Patient recall and revaccination
- Administration of ineffective medications
- Loss of faith in the organisation
- Litigation
- Staff hours spent on patient recall and management of incidents
- Reduction in supply of potent vaccines available for use
- Significant cost of replacement of inactive vaccines

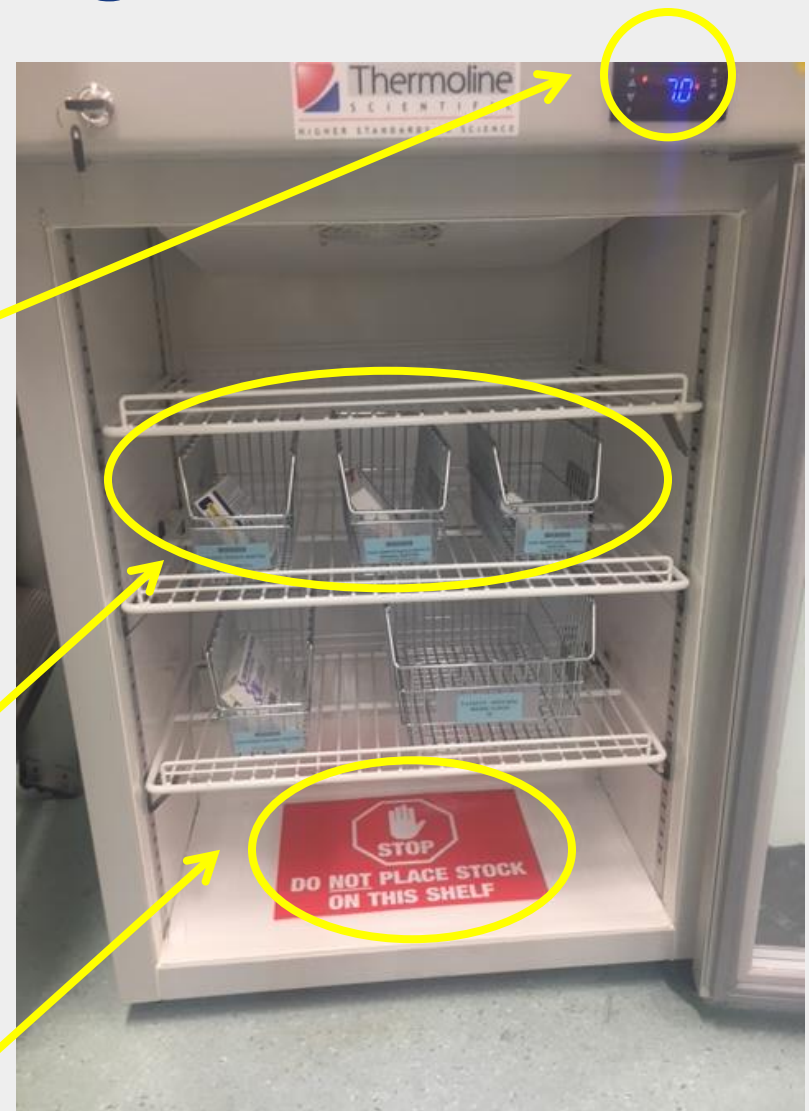
# Safe Vaccine Storage Management

- All vaccines and medications must be stored and managed according to National Vaccine Storage Guidelines *Strive for 5* 2<sup>nd</sup> Edition
- Vaccines should be stored in a purpose-built vaccine refrigerator
- Cold Chain Management is **EVERYONE'S** responsibility
- Monitor fridge temperatures twice daily, during department operating hours and record on the approved temperature chart
- All fridges must be continuously data logged with back to base monitoring
- Follow cold chain management policies and procedures
- Perform annual checks of all vaccine and medication storage equipment



# Refrigerator Stock Configuration

- Not overstocked
- Air gaps around all walls
- Within temperature range (7.0°C)
- Data logger will be positioned in the middle of the refrigerator
- Wire baskets used to facilitate air flow
- No stock on bottom shelf .  
Note sticker





DO NOT PLACE STOCK  
ON THIS SHELF

# Refrigerator Monitoring Equipment

## ALL VACCINE AND MEDICATION REFRIGERATORS MUST HAVE A DATA LOGGER

- Each fridge must be continuously monitored using a data logger
- Each manager responsible for a fridge will receive the data logger report weekly
- Data logger report must be printed, reviewed for excursions outside  $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$  (known as a cold chain breach) and reported.

# Refrigerator Monitoring Process

- Record minimum and maximum temperatures twice per day
- Reset the min/max thermometer after reading
- Record any events, such as deliveries, on the Temperature Monitoring Chart
- Follow cold chain breach protocol if temperature outside  $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$



BINDING MARGIN - NO WRITING

**VACCINE REFRIGERATOR TEMPERATURE CHART - FORTNIGHTLY**

Date range: 03 / 07 / 2017 to 16 / 07 / 2017

Facility: BANKSTOWN Location: WARD 2A

Fridge ID/name: WARD 2A FRIDGE

**Instructions for use**

Record and plot maximum, minimum and current temperatures on chart TWICE daily.  
 RESET temperature monitoring device after recording temperatures.  
 TAKE CORRECTIVE ACTION if temperatures out of range (+2 to +8°C) excluding fluctuations up to +12°C for ≤15 minutes.  
 Refer to cold chain breach steps below.



**Health**

	Date		3/7		4/7		5/7		6/7		7/7		8/7		9/7		10/7		11/7		12/7		13/7		14/7		15/7		16/7		
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	
Exact Time	0730	1815	0715	1830	0720	1825	0715	1845	0730	1830	0700	1900	0730	1815	0730	1830	0700	1845	0715	1845	0715	1900	0700	1800	1900	0730	1830	0715	1845		
Record Max Temp °C	6.4	7.2	6.8	6.3	6.5	6.6	6.5	6.4	6.5	6.2	6.0	7.2	7.8	6.3	6.2	6.1	6.0	6.8	6.7	6.7	6.6	6.0	6.1	5.9	6.1	5.9	6.1	7.8	6.0	5.9	
ACCEPTABLE TEMPERATURE STRIVE FOR 5°C	+12	Danger! Temperatures ABOVE 8 DEGREES are TOO WARM. TAKE IMMEDIATE CORRECTIVE ACTION																													
	+11																														
	+10																														
	+9																														
	+8																														
	+7																														
	+6																														
	+5																														
	+4																														
	+3																														
TOO WARM	+2																														
	+1																														
	0	Danger! Temperatures BELOW 2 DEGREES are TOO COLD. TAKE IMMEDIATE CORRECTIVE ACTION																													
	-1																														
	-2																														
Record Current Temp °C	5.0	5.1	5.2	5.0	5.3	5.1	4.9	4.8	5.3	5.6	4.7	4.9	5.2	5.6	5.0	4.9	5.5	5.8	5.0	5.1	5.5	5.4	5.0	4.9	5.3	7.8	5.1	5.1			
Record Min Temp °C	3.2	4.0	2.8	3.2	2.7	4.1	3.8	3.2	3.4	2.9	4.0	4.5	2.1	3.0	4.1	3.8	3.8	4.1	2.5	3.1	3.2	3.2	3.6	3.7	4.1	5.0	3.6	3.8			
Temperature RESET <input checked="" type="checkbox"/>	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Staff Signature	J	A	A	L	M	B	N	J	L	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A		

Results reviewed and appropriate action taken by person responsible

Name: JOHN DOE Designation: MANAGER Date: 16/7/17

**Document actions taken when temperatures outside +2°C to +8°C (excludes fluctuations up to +12°C ≤15 mins e.g. vaccine delivery)**

Date & Time	Temperature Current/Min/Max	Actions taken	Name (please print)	Staff Signature
15/7/17	MAX 7.8	Restocking fridge	JANE SMITH	J.S.

- COLD CHAIN BREACH STEPS (refer to Appendix 3 in 'Strive for 5')**
1. Take corrective action where possible. Ensure fridge door is closed, fridge is plugged in/turned on. Contact engineer if broken
  2. Immediately isolate the vaccines, keep refrigerated between +2°C and +8°C (move stock to another fridge) and label 'QUARANTINED STOCK - DO NOT USE'
  3. Label affected fridge 'OUT OF ORDER - DO NOT USE'
  4. Determine breach temperature and duration. Download data logging(s)
  5. Contact the local public health unit (PHU) on 1300 068 055 for advice. Do not discard any vaccines until advice is provided by the PHU (next working day if out of hours)
  6. Notify manager/delegate (next working day if out of hours)
  7. Report fridge temperature issues and actions on this chart
  8. Determine if anyone has received compromised vaccine. Discuss revaccination requirements with PHU as necessary
  9. Report the incident on IIMS (excludes breaches due to power outages)

**VACCINE REFRIGERATOR TEMPERATURE CHART - FORTNIGHTLY**

Date range: 03 / 07 / 2017 to 16 / 07 / 2017  
 Facility: BANKSTOWN Location: WARD 2A  
 Fridge ID/name: WARD 2A FREEZER

**Instructions for use**

Record and plot maximum, minimum and current temperatures on chart TWICE daily.  
 RESET temperature monitoring device after recording temperatures.  
 TAKE CORRECTIVE ACTION if temperatures out of range (+2 to +8°C) excluding fluctuations up to +12°C for ≤15 minutes.  
 Refer to cold chain breach steps below.



**Health**

	Date	3/7		4/7		5/7		6/7		7/7		8/7		9/7		10/7		11/7		12/7		13/7		14/7		15/7		16/7	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Exact Time		0730	185	0715	1830	0720	1825	0705	1800	0711	1800	0700	1815	0730	1815	0715	1830	0723	1830	0700	1800	0730	1845	0715	1845	0700	1800	0715	1830
Record Max Temp °C		-11	-10	-15	-13	-10	-11	-10	-12	-13	-11	-10	-10	-11	-12	-13	-13	-12	-11	-10	-11	-11	-15	-14	-12	-11	-10	-12	-13
ACCEPTABLE TEMPERATURE STRIVE FOR °C	TOO WARM	Danger! Temperatures ABOVE 7 DEGREES are TOO WARM. TAKE IMMEDIATE CORRECTIVE ACTION																											
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Record Current Temp °C		-16	-18	-16	-17	-17	-18	-18	-19	-18	-16	-17	-16	-18	-18	-19	-20	-18	-19	-19	-18	-17	-18	-18	-20	-18	-19	-20	-18
Record Min Temp °C		-22	-20	-21	-24	-23	-24	-28	-26	-25	-24	-28	-25	-23	-22	-24	-24	-25	-26	-25	-26	-27	-28	-28	-22	-23	-23	-24	-25
Temperature RESET <input checked="" type="checkbox"/>		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Staff Signature		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	

Results reviewed and appropriate action taken by person responsible

Signature: JOHN COE Designation: MANAGER Date: 16/7

**Document actions taken when temperatures outside +2°C to +8°C (excludes fluctuations up to +12°C ≤15 mins e.g. vaccine delivery)**

Date & Time	Temperature Current/Min/Max	Actions taken	Name (please print)	Staff Signature

- COLD CHAIN BREACH STEPS** (refer to Appendix 3 in 'Strive for 5')
1. Take corrective action where possible. Ensure fridge door is closed, fridge is plugged in/turned on. Contact engineer if broken
  2. Immediately isolate the vaccines, keep refrigerated between +2°C and +8°C (move stock to another fridge) and label 'QUARANTINED STOCK - DO NOT USE'
  3. Label affected fridge 'OUT OF ORDER - DO NOT USE'
  4. Determine breach temperature and duration. Download data logging(s)
  5. Contact the local public health unit (PHU) on 1300 066 055 for advice. Do not discard any vaccines until advice is provided by the PHU (next working day if out of hours)
  6. Notify manager/delegate (next working day if out of hours)
  7. Report fridge temperature issues and actions on this chart
  8. Determine if anyone has received compromised vaccine. Discuss revaccination requirements with PHU as necessary
  9. Report the incident on IIMS (excludes breaches due to power outages)

Refer to the current edition of the National Vaccine Storage Guidelines (Series for 5) for detailed advice on vaccine cold chain management and storage

# Hanwell Monitoring System

- Temperature transmitter probes are installed on every refrigerator and freezer where medication is stored
- Temperature readings are taken every 2 minutes and transmitted to a central server
- All alarm events (including who acknowledged them and any actions taken) are also recorded
- The system will alarm whenever there is a temperature breach
- The GREEN alarm status icon below will be seen when viewing via the web browser when all refrigerators are within limits

Welcome: Admin User

Alarms unacknowledged: 0

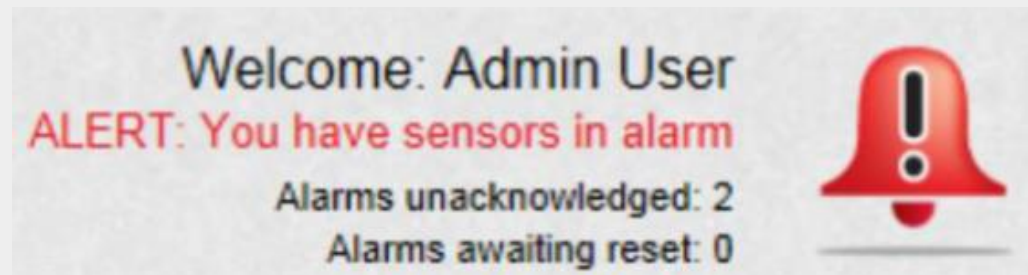
Alarms awaiting reset: 0





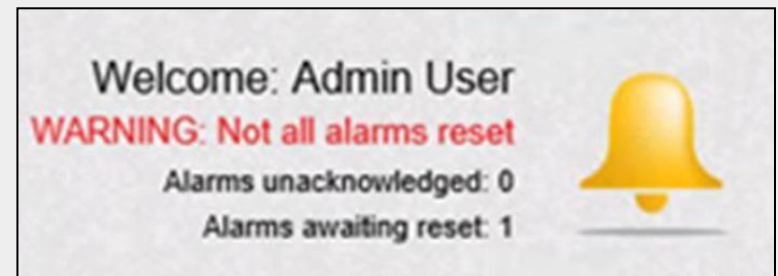
# Hanwell Monitoring System - Acknowledge

- A RED alarm status icon means that there is currently an ACTIVE alarm that has NOT been acknowledged
- Alarms can be acknowledged via the Central Alarm Panel **OR** via SMS
- For detailed instructions on how to 'Acknowledge' alarms, see ***SWSLHD policy 'Cold Chain Management for Temperature Sensitive Medication and Vaccines' SWSLHD\_2017\_XXX – Appendix 10***



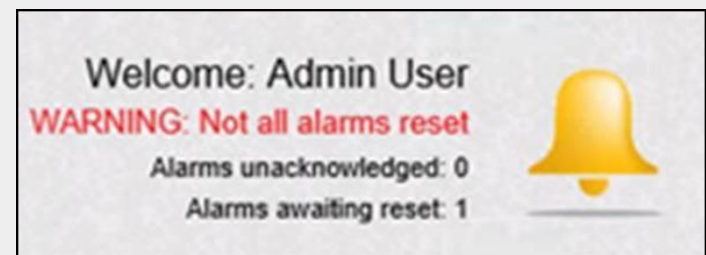
# Hanwell Monitoring System - Acknowledge

- The purpose of acknowledging the alarm is to inform other users that someone is aware of the alarm and has accepted responsibility for investigating the temperature breach
- It does NOT mean that the temperature breach has returned to normal
- A YELLOW alarm will be seen once the alarm has been acknowledged awaiting resetting of the alarm once the issue has been resolved



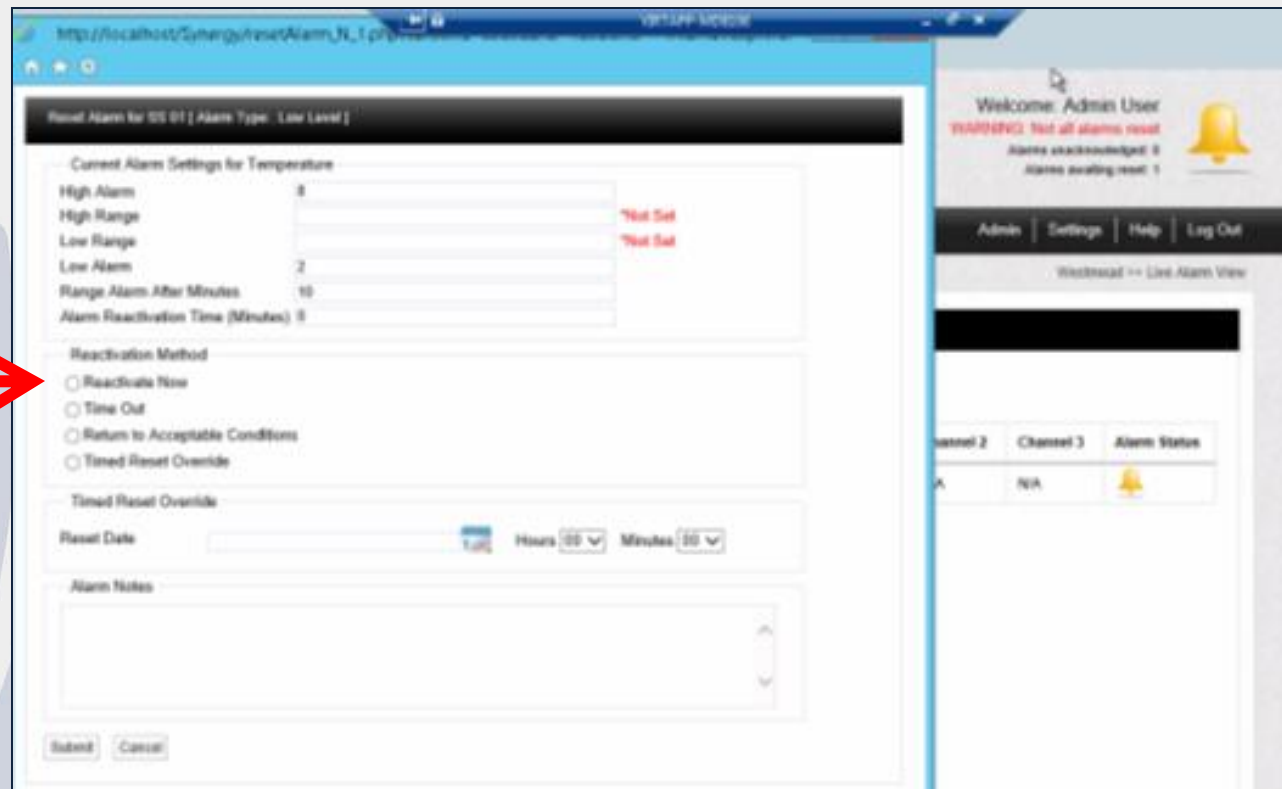
# Hanwell Monitoring System - Resetting

- It is the responsibility of the NUM or person In-Charge of the area where the alarm has been activated to acknowledge and reset the alarm
- Resetting the alarm clears the alarm and returns the alarm monitoring to normal
- Alarms must ONLY be reset if the event causing the alarm has been resolved and the refrigerator or freezer is within normal limits
- If the alarm is reset while the refrigerator is still in 'alarm condition' it will re-alarm




# Hanwell Monitoring System - Resetting

To reset the alarm on the webpage choose **'Reactivate Now'** under the Reactivation Method once the temperature has returned to normal limits



The screenshot displays the 'Reset Alarm for 00 01 | Alarm Type: Low Level' configuration page. The 'Current Alarm Settings for Temperature' section includes fields for High Alarm (3), High Range (Not Set), Low Range (Not Set), Low Alarm (2), Range Alarm After Minutes (10), and Alarm Reactivation Time (Minutes) (5). The 'Reactivation Method' section has four radio button options: 'Reactivate Now', 'Time Out', 'Return to Acceptable Conditions', and 'Timed Reset Override'. The 'Timed Reset Override' section features a 'Reset Date' field and dropdowns for 'Hours' (00) and 'Minutes' (00). An 'Alarm Notes' text area is located at the bottom of the settings. A red arrow points from the text above to the 'Reactivate Now' radio button. The right sidebar shows a 'Welcome: Admin User' message with a yellow bell icon and a table with columns 'Channel 2', 'Channel 3', and 'Alarm Status'. The 'Alarm Status' column contains a yellow bell icon. The bottom right corner of the page shows the word 'health'.

Channel 2	Channel 3	Alarm Status
A	NA	

# Hanwell Monitoring System – Trouble Shooting

- Restocking
  - avoid pushing the refrigerator into 'Alarm' mode
  - Frequent restocking of smaller amounts will have less impact on internal temperatures than a large restock.
- Physical obstruction
  - Door left open, air vents blocked
  - Power unplugged /switched off
  - Overcrowding
- Device issues
  - Refrigerator fan /compressor failure

Welcome: Admin User

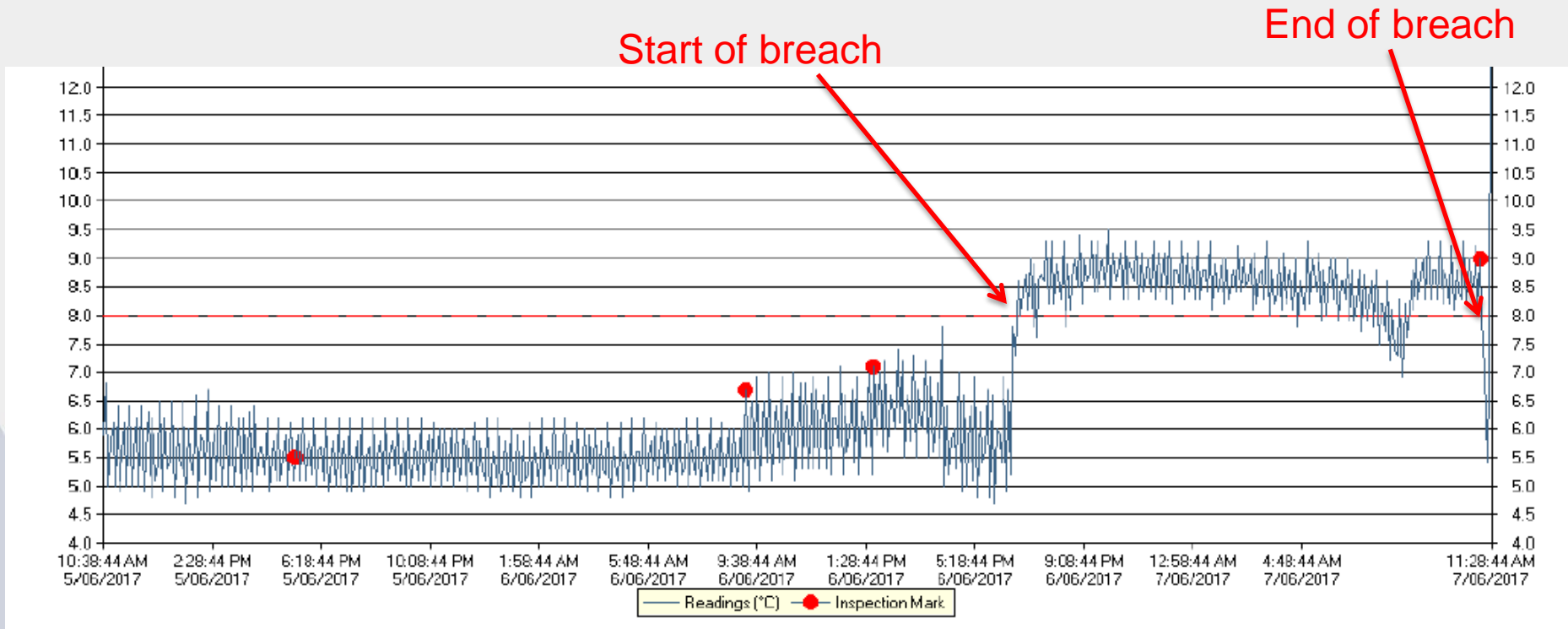
Alarms unacknowledged: 0

Alarms awaiting reset: 0



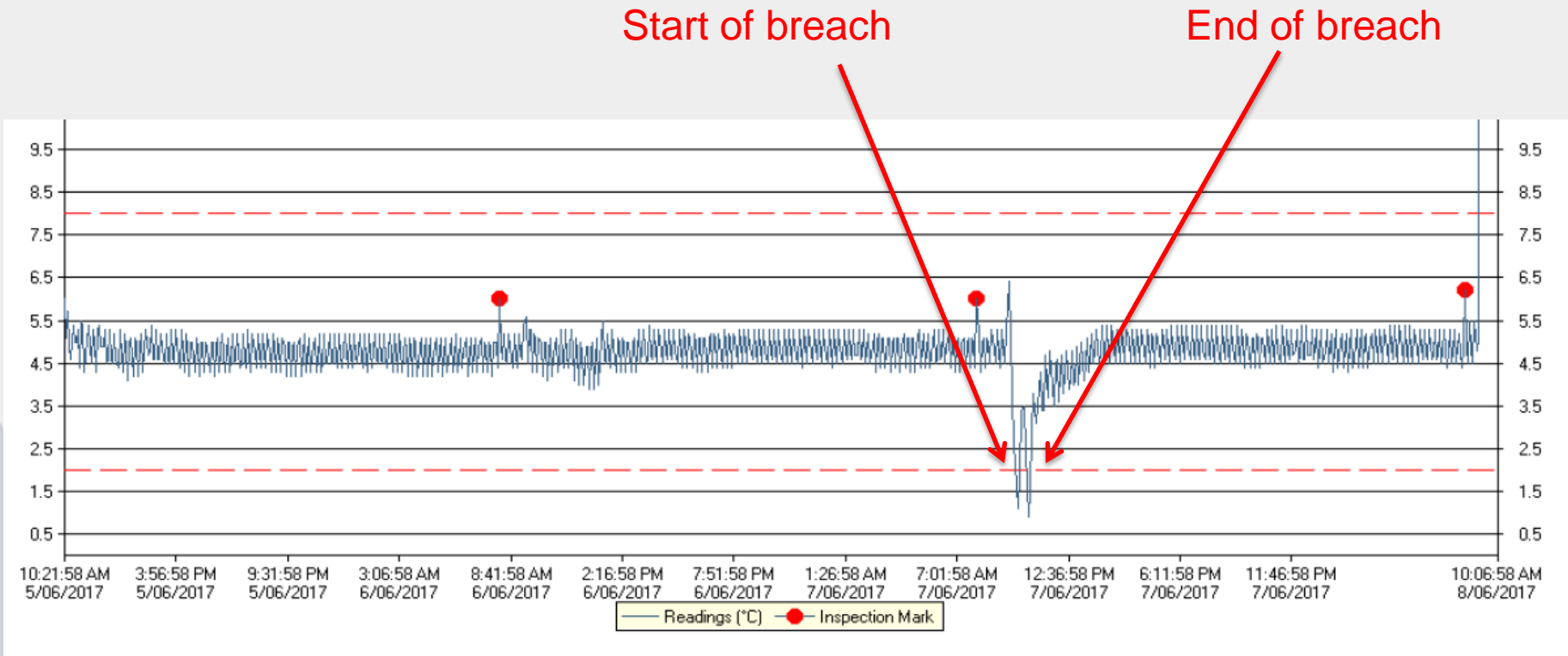


# Example data logging graph of a high cold chain breach



If a breach occurs, follow SWSLHD Cold Chain Breach Escalation process

# Example data logging graph of a low cold chain breach



If a breach occurs, follow SWSLHD Cold Chain Breach Escalation process



# Cold Chain Breach

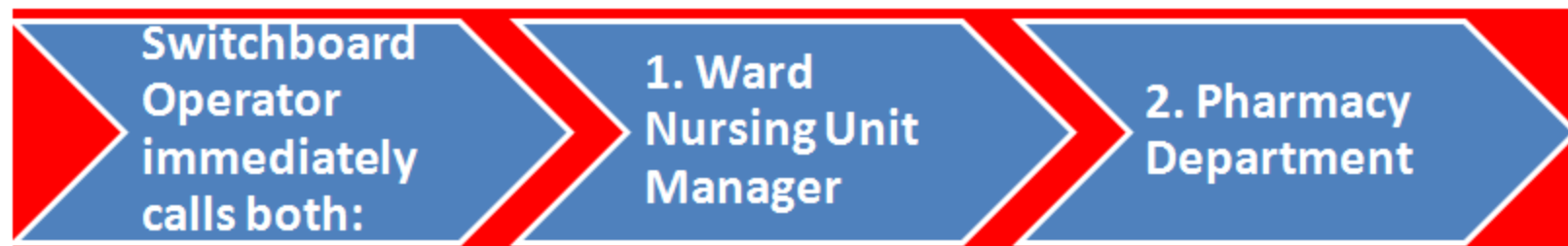
In the event of a Cold Chain Breach i.e temperature outside the range of +2°C and +8°C the SWSLHD Cold Chain Breach Escalation pathway is activated immediately.

# Refrigeration Alarm Escalation Pathway for Switchboard Staff

## SWSLHD

In the event there is alarm activation for *any* refrigerator unit in the facility, Switchboard staff are to immediately follow the escalation pathway:

### 1) Business Hours (Monday-Friday 0800-1630hr excluding public holidays):



### 2) After Hours (all other times except business hours):



*Switchboard staff to contact the facility Operational Nurse Manager in business hours or Executive On-Call after hours with escalation.*

## Refrigeration Alarm Escalation Pathway for Bowral & District Hospital

In the event there is alarm activation for *any* refrigerator unit in the facility, staff are to immediately follow the escalation pathway:

### 1) Business Hours (Monday-Friday 0800-1630hr excluding public holidays):



### 2) After Hours (all other times except business hours):



*Staff to contact the facility Operational Nurse Manager in business hours or Executive On-Call after hours with escalation issues*

*Written notification to be sent to pharmacy at all times*

## Refrigeration Alarm Escalation Pathway for Primary and Community Health

In the event that there is an alarm for ANY vaccine or medication refrigerator unit in any of the facilities, staff are to immediately follow the escalation pathway:

### **1) Business hours (Monday to Friday 0800-1630 excluding public holidays)**

Operational Nurse  
Manager immediately  
calls both :

1. Facility Nursing Unit  
Manager

2. Pharmacy

### **2) After Hours (all other times except business hours)**

Executive On - call  
acknowledges text , logs  
on to Hanwell website  
to assess risk and either:

1. Actions immediately  
OR

2. Actions next business  
day

***Staff are to contact the Operational Nurse Manager in business hours or Executive On Call in business hours or Executive On-Call after hours with escalation issues.***

***Written notification to be sent to Pharmacy at all times***

# Cold Chain Breach Escalation Pathway

## TEMPERATURE FOUND TO BE OUTSIDE THE RECOMMENDED RANGE OF +2°C AND +8°C.

This **excludes** fluctuations of up to 12 degrees for less than 15 minutes (for example when restocking the fridge or rotating stock).

### Ward Role:

- If temperature currently within range – quarantine stock **inside** fridge. **DO NOT DISCARD STOCK.**
- If temperature out of range – move quarantined stock to alternative medication fridge (another ward or to pharmacy)
- Place sign **"STOP! DO NOT USE THIS STOCK"** on the outside of the fridge door.
- Review transmitter probe information online.
- In business hours - Ward Manager or Team Leader to notify Pharmacy, providing transmitter probe information and vaccine refrigerator temperature chart recordings.
- Out of business hours - After Hours Manager to be notified, escalating to Pharmacist on Call if required.
- Source alternative stock within facility until further notice.
- Document the date and time breach identified and reported on the vaccine refrigerator temperature chart.
- Complete IIMS once impact on stored medications is determined by Pharmacy or Public Health Unit.

### Pharmacy Role:

- Ensure stock is adequately quarantined and appropriately labelled.
- Review transmitter probe information and vaccine refrigerator temperature chart from affected fridge.
- Determine impact on the medication inside the fridge. Record the outcome and keep on file.
- Escalate to Operational Nurse Manager, further escalating to General Manager if stored medication is affected.
- Decommission and Recommission the transmitter probe if refrigerator is shut down for repairs.

### IF VACCINES STORED IN THIS FRIDGE ... THEN

- Pharmacy to contact Public Health Unit (PHU) on 1300 066 055 in business hours.
- Await advice on actions required due to breach.
- Record the outcome and keep record on file.

### Public Health Unit Role:

- Review data and information supplied by facility to identify if a vaccine Cold Chain Breach has occurred.
- Advise Health Protection NSW who will formulate actions to be implemented as required.
- Liaise with facility to follow up actions as required.

see handout

# Power outages

To salvage vaccines and medications:

1. Immediately quarantine the vaccines, keep the fridge door closed and attach a 'Quarantine' sign
2. Closely monitor fridge temperature via the data logger readings on the Hanwell website
3. If the temperatures gradually progress towards 8°C, follow the escalation plan



**DO NOT USE THIS STOCK.**

A cold chain breach is suspected, therefore all stock is quarantined until further notice from Pharmacy. Please contact Pharmacy/AHNM if stock is required or for further information.

# Common Issues resulting in Cold Chain breaches

- Overstocking
- Variety of refrigerators and data loggers
- Irregular servicing of vaccination and medication refrigerators
- Staff unsure of quarantine procedures
- Transporting from Pharmacy to the ward



# Tips

- If in doubt... **QUARANTINE!** (you can source vaccines and medications from another department or pharmacy)
- Don't put vaccines or medications in your pocket, even for a short time
- Don't leave the refrigerator door open
- Angle the refrigerator up slightly at the front to facilitate auto-closing of the door
- Only remove vaccines for immediate use
- Check temperature before opening the door every time
- Check expiry dates and use oldest first
- Ensure valid medication order is present before removing vaccine

# Summary

- Correct temperature range
- Monitoring and recording
- Storage considerations
- Escalation
- Quarantine

# Local Vaccine / Medication Refrigerator Practical Demonstration

- Monitoring and recording temperature
- Stock configuration
- Signage
- Reset button
- Data Logger position

# For more information...

- National Vaccine Storage Guidelines. Strive for 5  
2nd Edition

[http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/D7EDA378F0B97134CA257D4D0081E4BB/\\$File/strive-for-5-guidelines.pdf](http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/D7EDA378F0B97134CA257D4D0081E4BB/$File/strive-for-5-guidelines.pdf)

**•Cold Chain Management for Temperature Sensitive Medication and Vaccines SWSLHD\_2017\_XXX**

# Acknowledgement

- Barbara Wilson, Immunisation Coordinator, Albury Public Health Unit, for providing cold chain information and images